

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

**In re Novartis and Par Antitrust
Litigation**

CASE NO. 1:18-CV-04361-AKH

This Document Relates to:

All Actions

**MEMORANDUM OF LAW IN SUPPORT OF NON-PARTIES
LUPIN LTD. AND LUPIN PHARMACEUTICALS, INC.'S OPPOSITION TO
PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF DOCUMENTS
RESPONSIVE TO RULE 45 SUBPOENA**

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Non-parties Lupin Limited and Lupin Pharmaceutical, Inc. (collectively, “Lupin”) respectfully submit this opposition to Plaintiffs’ Motion to Compel Third Parties Lupin Limited and Lupin Pharmaceuticals, Inc. to Produce Documents Responsive to Rule 45 Subpoena.

PRELIMINARY STATEMENT

Since Plaintiffs first served a Subpoena on non-party Lupin in December 2018, Lupin has held numerous discussions with its employees in the United States, searched for responsive documents at multiple locations in the United States and India, and produced more than 20,000 pages of documents and gigabytes of electronic data to Plaintiffs. That material included, but was not limited to: (i) Lupin’s entire ANDA file for generic Exforge and generic Exforge HCT; (ii) its Paragraph IV notice sent to Novartis with respect to Exforge; (iii) Lupin organizational charts; (iv) launch preparation documents, including New Product Launch meeting minutes; (v) manufacturing documents; and (vi) transactional sales and chargeback data.

Every time Lupin produced documents, Plaintiffs demanded more. Lupin diligently searched for those additional documents, and often produced more responsive material. Finally, Lupin informed Plaintiffs in April of this year that it had searched for the last of the demanded documents, but was unable to locate any further responsive material. Weeks passed with no word from Plaintiffs, which was not surprising, because Lupin was not refusing to search for, and was not withholding, responsive documents.

Then Plaintiffs filed this Motion to Compel production of the documents Lupin had searched for, but could not find. If Plaintiffs’ goal is to impose a continuing significant burden on Lupin—both in terms of legal costs and resources—they are executing their strategy successfully. If their goal is to obtain documents, they are wasting the Court’s time, because they already have the information they need. Plaintiffs’ eighteen-month-long moving target

approach has imposed on Lupin costs far beyond what is reasonable to ask of a third party, and we respectfully ask that the Court deny the Motion to Compel.

FACTUAL BACKGROUND

A. Lupin's Limited Relevance to This Litigation

Plaintiffs allege the existence of an unlawful “pay-for-delay” agreement between Defendants Par and Novartis to monopolize the market for amlodipine/valsartan, or generic Exforge. As Plaintiffs allege, this illegal agreement delayed entry into the market for generic Exforge by Par and other generic manufacturers, including Lupin, causing higher prices for amlodipine/valsartan tablets and damages to Plaintiffs. *Amended Complaint And Jury Trial Demand* at 2, 5 (ECF No. 139). Under Plaintiffs’ theory, Par would have entered the market for generic Exforge earlier than it actually did, and other generic manufacturers of Exforge, including Lupin, could also have launched earlier. *Id.* Given Lupin’s limited relevance to the claims and defenses at issue, Plaintiffs’ fifty-one-page Amended Complaint mentions Lupin a total of four times. *Id.* at 37, 40, 41.

B. The Subpoenas to Lupin and the Eighteen-Month Meet and Confer Process

On December 18, 2018, Plaintiffs first served Lupin Pharmaceuticals, Inc. with their Subpoena containing 22 separate categorical requests for production. Declaration of Zarema Jaramillo (“Jaramillo Decl.”) ¶ 2. Lupin responded and objected to the Subpoena on January 18, 2019. *Id.* ¶ 3. Plaintiffs subsequently served the Subpoena on both Lupin Pharmaceuticals, Inc. and Lupin Ltd., and Lupin responded and objected accordingly. *Id.* ¶ 6.¹ Lupin met and conferred with Plaintiffs twice in March 2019, resulting in Lupin’s initial agreement to search for and produce documents responsive to eight of Plaintiffs’ 22 requests. Relevant to this Motion,

¹ Plaintiffs also served the Subpoena on Lupin’s wholly-owned subsidiary, Novel Laboratories, Inc. (“Novel”). Although Plaintiffs have not moved to compel Novel’s compliance with the Subpoena, Lupin includes reference to the subpoena to Novel herein for purposes of completing the record concerning Lupin’s (and Novel’s) efforts to comply with the Subpoenas.

Lupin agreed to produce “minutes from Lupin’s New Product Launch meetings that discuss Generic Exforge or Generic Exforge HCT Launch plans” and “documents sufficient to show Lupin’s ability to scale-up and launch Generic Exforge and Generic Exforge HCT, to the extent such documents are available.” Declaration of Dan Chiorean (“Chiorean Decl.”), Ex. 12. When Plaintiffs requested that Lupin produce additional documents regarding launch and manufacturing, Lupin did not agree to do so, and rather inquired whether Plaintiffs would agree to, cost shifting as to these two categories of documents, given the burden that Lupin would incur to comply with the request. Notably, Plaintiffs never responded to Lupin’s inquiry regarding cost shifting. Jaramillo Decl. ¶ 9.

In the meantime, following its reasonably diligent search, Lupin made responsive productions to Plaintiffs on April 26, 2019, June 14, 2019, August 5, 2019, October 8, 2019, and February 28, 2020, consisting of its entire ANDA file for generic Exforge and generic Exforge HCT, its relevant Paragraph IV notice sent to Novartis, Lupin organizational charts, its transactional sales and chargeback data for generic Exforge and generic Exforge HCT, and documents related to launch preparation for and manufacturing of generic Exforge and generic Exforge HCT. Jaramillo Decl. ¶¶ 10-13. However, Lupin’s efforts to negotiate a reasonable scope of non-party discovery were not reciprocated, and Plaintiffs continued to attempt to expand the scope of Lupin’s production, repeatedly setting unreasonable and artificial deadlines and repeatedly threatening to move to compel if their deadlines were not met. *Id.* ¶¶ 15, 17.

After nine months of negotiation and rolling productions, Lupin wrote to Plaintiffs on September 2, 2019, noting that it had not located any additional documents responsive to the Subpoena, but that its reasonable search was ongoing, and any further responsive documents identified would be produced. Lupin stated to Plaintiffs that “the documents produced so far

show when the companies [*i.e.*, Lupin and Novel] received FDA approval, when they began marketing generic Exforge, and how much generic Exforge they have sold since launch” and requested Plaintiffs to “explain what additional information belonging to these third-parties is necessary for Plaintiffs to continue litigating their antitrust case against Par and Novartis.” *Id.* ¶ 16 & Ex. 8. Plaintiffs responded more than three weeks later, again reflexively demanding additional productions, but failing to address the key question Lupin posed. Chiorean Decl. Ex. 9.

Together with its October 2019 production, Lupin wrote to Plaintiffs that documents already produced evidenced that Novel was still responding to questions from the FDA in the course of its generic Exforge ANDA review process in January 2015. As such, Lupin wrote, the evidence reflected that “Novel launched immediately upon FDA approval of its ANDA.” Chiorean Decl. Ex. 10. Plaintiffs did not respond substantively to this correspondence, either. Three months later, on January 13, 2020, Plaintiffs wrote to Lupin, demanding that it produce additional documents. *Id.* Ex. 11. Plaintiffs subsequently emailed Lupin on January 29, 2020 to further demand that it produce additional launch preparation documents. Jaramillo Decl. ¶ 22 & Ex. 9. Lupin responded the same day, identifying to Plaintiffs by Bates range the Lupin and Novel launch preparation documents it had already produced. *Id.* ¶ 23.

Reflexively, Plaintiffs wrote again to Lupin on February 3, 2020, demanding, among other things, that Lupin produce additional launch preparation documents. *Id.* ¶ 24 & Ex. 10. Plaintiffs claimed that Lupin “already committed to produce” additional launch preparation documents, but Plaintiffs’ basis for this statement is Lupin’s March 29, 2019 and April 19, 2019 correspondence, neither of which actually reflects such an agreement by Lupin. *Id.* As noted *infra*, Lupin inquired in April 2019 whether Plaintiffs would agree to shift costs in exchange for

production of these documents, but Plaintiffs never responded to Lupin's inquiry. Chiorean Decl. Ex. 2. Nevertheless, on February 28, 2020, Lupin made a small supplemental production of additional launch preparation and manufacturing documents that it had located following an additional reasonable search. Jaramillo Decl. ¶ 25 & Ex. 11.

On March 10, 2020, Lupin met and conferred again with Plaintiffs. This time, Plaintiffs requested (among other things) additional launch preparation and manufacturing documents from Lupin's facility in Goa, India. *Id.* ¶ 26. Days later, the COVID-19 pandemic began significantly impacting the U.S. Lupin Ltd. is located in India, which entered lockdown in late March. *Id.* ¶ 27. On April 7, 2020, Plaintiffs wrote to Lupin demanding production of "missing" documents and again, threatening to seek relief from the Court. *Id.* ¶ 28 & Ex. 12. Given the ongoing complications caused by the global pandemic, we responded that same day to confirm that we were still working to determine whether Lupin had any other documents responsive to the Subpoenas. *Id.* ¶ 29 & Ex. 13.

On April 10, Plaintiffs wrote to Lupin, again falsely claiming that Lupin had agreed to produce the sought launch preparation documents in April 2019, and demanding that Lupin produce them. *Id.* ¶ 30 & Ex. 14. On April 17, 2020, having located no additional responsive documents despite a multi-year reasonable search, Lupin responded, confirming that it had fully complied with Plaintiffs' Subpoena through its rolling productions and noting further that Lupin's production reflected that it did not have FDA approval to launch generic Exforge until March 2015. Chiorean Decl., Ex. 3. Six weeks later, Plaintiffs filed this Motion, seeking production of nine categories of Lupin launch preparation and manufacturing documents from Lupin, none of which were addressed in the parties' 2020 correspondence or meet and confers.

In sum, over the course of eighteen months of meeting and conferring, Lupin invited Plaintiffs to identify what additional evidence Plaintiffs required from Lupin to litigate their case against Par and Novartis. Lupin further explained the extreme burden Plaintiffs' Subpoena posed on it. Plaintiffs did not—and could not—articulate any reason why the scope of discovery in this case is any different from prior pay-for-delay cases in which Lupin's prior productions were sufficient, nor did they articulate a basis for seeking the additional documents from Lupin, other than that the evidence produced to date does not support the story Plaintiffs would like to tell about Lupin's manufacture and launch of generic Exforge. That is simply not the standard for requiring compliance with a non-party subpoena. Lupin would incur tremendous burden to comply with these requests, and Plaintiffs' Motion should be denied.

ARGUMENT

As evidenced by the long history of the back-and-forth communication with Plaintiffs summarized above, Lupin has more than complied with its obligations as a non-party. Subpoenas issued pursuant to Rule 45 must comply with the relevance and proportionality requirements of Rule 26(b)(1). *Malibu Media, LLC v. Doe*, No. 15-cv-3147, 2016 WL 5478433, at *2 (S.D.N.Y. Sept. 29, 2016). Rule 26 limits discovery to documents and information “relevant to any party’s claim or defense and proportional to the needs of the case.” Fed. R. Civ. P. 26(b)(1). And courts “must limit the . . . extent of discovery” to that scope. Fed. R. Civ. P. 26(b)(2)(C)(iii). The purpose of these limitations is “to encourage judges to be more aggressive in identifying and discouraging discovery overuse by emphasizing the need to analyze proportionality before ordering production of relevant information.” *Henry v. Morgan’s Hotel Group, Inc.*, No 15-cv-1789, 2016 WL 303114, at *3 (S.D.N.Y. Jan. 25, 2016).

In particular, “where, as here, the discovery is sought from a non party, the Court should be particularly sensitive to weighing the probative value of the information sought against the

burden of production on the non party.” *Fears v. Wilhelmina Model Agency, Inc.* No. 02 Civ. 4911, 2004 WL 719185, at *1 (S.D.N.Y. Apr. 1, 2004); *see also Tucker v. Am. Int’l Grp.*, 281 F.R.D. 85, 92 (D. Conn. 2012) (“[T]he fact that discovery is being sought *from a third or non-party* . . . weighs against permitting discovery”). Thus, in determining whether a subpoena subjects a non-party to undue burden pursuant to Rule 45(d)(3)(A)(iv), courts “weigh the burden to the subpoenaed party against the value of the information to the serving party by considering factors such as relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed.” *Citizens Union of City of N.Y. v. Att’y Gen. of N.Y.*, 269 F. Supp. 3d 124, 138 (S.D.N.Y. 2017); *see also* Fed. R. Civ. P. 45(d)(3)(A)(iv) (Court shall quash or modify a subpoena that “subjects a person to undue burden”). And, as the propounding party, Plaintiffs “bear[] the burden of proving that compliance with its document request would not impose ‘significant expense’ or ‘undue burden’” on Lupin in violation of Rule 45. *In re Subpoena Duces Tecum Served on Bell Comm’n Research, Inc.*, No MA-85, 1997 WL 10919, at *2 (S.D.N.Y. Jan. 13, 1997). Plaintiffs cannot meet this burden.

I. LUPIN HAS SATISFIED ITS OBLIGATIONS UNDER RULES 26 AND 45

Lupin has produced to Plaintiffs more than 20,000 pages of responsive material, not including the nearly 20,000 additional pages that Novel produced to Plaintiffs. Lupin’s production appropriately balances the parties’ need for this discovery against Lupin’s rights to avoid undue burden and expense as a non-party with minimal relevance to this litigation. The nine broad categories that Plaintiffs now move to compel Lupin to produce seek to establish Plaintiffs’ theory that Lupin would have been ready, willing, and able to market generic Exforge earlier than March 2015. *See Memorandum Of Law In Support Of Plaintiffs’ Motion To Compel Third Parties Lupin Limited And Lupin Pharmaceuticals, Inc. To Produce Documents*

Responsive To Rule 45 Subpoena at 5 (ECF No. 245) (“Pls. Mem.”) (arguing that absent the alleged “pay-for-delay” agreement between Par and Novartis, Par would have entered the market earlier . . . and in turn other generic companies such as Lupin would also have entered the market earlier than they actually did”). Lupin’s document production—including its forecasts, ANDA file, New Product Launch meeting minutes, transactional data, and launch preparation documents—is sufficient evidence that, contrary to Plaintiffs’ theory, Lupin simply could not have entered the market for generic Exforge any earlier. Indeed, the ANDA file Lupin produced clearly states when the FDA granted Lupin final approval for generic Exforge and generic Exforge HCT.

Plaintiffs’ dissatisfaction with the facts as they are does not entitle them to any additional discovery. Anything more would be in an effort to uncover potential additional claims, which is not the purpose of discovery. *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, No. 11 CIV. 0071 (PGG), 2015 WL 13649823, at *2 (S.D.N.Y. July 29, 2015) (“[D]iscovery may not be used as a fishing expedition to discover additional instances of wrongdoing beyond those already alleged” (quoting *Barbara v. MarineMax, Inc.*, No. 12-CV-368 (ARR) (RER), 2013 WL 1952308, at *2 (E.D.N.Y. May 10, 2013))). Regardless, Plaintiffs have not shown that any additional discovery from Lupin is necessary or justified. *In re Weatherford Int’l Sec. Litig.*, No. 11 Civ. 1646 (LAK)(JCF), 2013 WL 5788687, at *3 (S.D.N.Y. Oct. 28, 2013) (“But pointing to one example of potentially discoverable material does not transform an overbroad request into one that is ‘properly tailored.’”); *see also Zukoski v. Phila. Elec. Co.*, No. CIV. A. 93-4780, 1994 WL 637345, at *3 (E.D. Pa. Nov. 14, 1994) (“It is a generally accepted rule that standards for non-party discovery require a stronger showing of relevance than for party discovery.”).

Any further discovery from Lupin would be of minimal marginal value, particularly balanced against the significant burden Lupin would incur to produce it. Plaintiffs' demands are disproportionate, and their Motion to Compel should be denied.

II. PLAINTIFFS' REQUESTS IMPOSE AN UNDUE BURDEN ON LUPIN THAT IS DISPROPORTIONATE TO THE NEEDS OF THE CASE.

Lupin already has produced documents sufficient to satisfy its obligations under Rules 26 and 45. When deciding whether to enforce a subpoena, courts "must weigh the probative value of the information against the burden of production" on the non-party. *In re Biovail Corp. Sec. Litig.*, 247 F.R.D. 72, 74 (S.D.N.Y. 2007); *see also Arista Records LLC v. Lime Grp.*, No. 06-CV-5936(KMW), 2011 WL 781198, at *2-3 (S.D.N.Y. Mar. 4, 2011) (denying motion to compel because "the burden of collecting, searching, reviewing, and producing" the requested documents "would significantly outweigh any potential probative value, particularly here, where the burden would be imposed on non-parties"); *Jack Frost Labs., Inc. v. Physicians & Nurses Mfg. Corp.*, No. 92 CIV. 9264 (MGC), 1994 WL 9690, at *2 (S.D.N.Y. Jan. 13, 1994) ("The most obvious burden is borne by the non-party witness, and we are instructed to be particularly sensitive to any prejudice to non-litigants drawn against their will into the legal disputes of others."). Plaintiffs' nine categorical requests are sweepingly broad, and Lupin has been unable to locate and produce responsive documents despite more than 18 months of reasonable good faith searches. Plaintiffs have utterly failed to follow the dictates of Rule 45(d)(1) and take reasonable steps to mitigate the burden on Lupin of complying with the Subpoena. Nor have Plaintiffs showed the specific tangential value its requests would provide when compared to the burden imposed on Lupin. *Corbett v. eHome Credit Corp.*, No. 10-CV-26 (JG)(RLM), 2010 WL 3023870, at *4 (E.D.N.Y. Aug. 2, 2010). Indeed, Plaintiffs cite nothing specific to Lupin—or even to this case—that requires production of the documents sought on this Motion.

Plaintiffs’ reliance on Magistrate Judge Francis’ ruling in *Namenda* is misplaced. *In re Namenda Direct Purchase Antitrust Litig.*, No. 15 Civ. 7488 (CM)(JCF), 2017 WL 3822883 (S.D.N.Y. Aug. 30, 2017). In that *Namenda* dispute, which involved the same Plaintiffs and Lupin, Lupin had filed an ANDA to launch its generic Namenda before the expiration of the relevant patent. *Id.* at *1. Lupin was accordingly sued for patent infringement by the brand manufacturer, and in settling the patent litigation, agreed not to launch its generic until July 2015. *Id.* Here, by contrast, Lupin filed its ANDA after the relevant patent had expired, was not sued by, and therefore did not—and could not—settle with Novartis. Lupin’s tangential role in this litigation is thus even more attenuated than was its role in *Namenda*. Additionally, in *Namenda*, Judge Francis concluded that Lupin’s agreement with the plaintiffs to produce “high-level” documents related to launch plans encompassed the documents sought in the *Namenda* plaintiffs’ motion to compel. *Id.* at *5. Guided by the *Namenda* precedent, Lupin here already has produced documents sufficient to show its launch plans, including but not limited to its New Product Launch meeting minutes for the relevant time period. *See* Jaramillo Decl. ¶ 35 & Ex. 17. The ruling in *Namenda* is thus wholly distinguishable and provides no support for Plaintiffs’ position on this Motion.²

Indeed, this Court has already rejected Plaintiffs’ prior attempts to force compliance with their overbroad subpoena on other third party generic manufacturers. *Order Denying Motion To Compel*, (ECF No. 164). Like Lupin, non-party Mylan negotiated a response to Plaintiffs’ Rule 45 subpoena and produced thousands of pages of responsive documents. *Memorandum Of Law In Support Of Non-Party Mylan’s Opposition To Plaintiffs’ Motion To Compel*, (ECF No. 162).

² The other cases Plaintiffs cite are equally inapposite. The summary judgment opinion in *Namenda* referred generally to the evidence produced in discovery but did not opine on (or even address) the appropriate scope of the relevant non-party subpoenas. *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 169-70 (S.D.N.Y. 2018).

Plaintiffs demanded more, and moved to compel additional production from Mylan. This Court denied Plaintiffs' motion, holding that Mylan's production was "sufficient" and therefore the additional discovery Plaintiffs sought was "disproportional, unduly burdensome, and thus, unwarranted." *Order Denying Motion To Compel*, (ECF No. 164). The same result is warranted here.

Lupin's document production already fully satisfies Plaintiffs' requests, and any additional production would be immaterial and unduly burdensome on Lupin. Plaintiffs' cavalier statement that "Lupin is not lacking in resources" (Pls. Mem. at 13) is simply not the standard for demanding discovery under Rules 26 and 45. To the extent Plaintiffs protest that Lupin has insufficiently described the burden it would bear to comply with the Subpoenas, those cries ring hollow. Lupin has already spent more than eighteen months endeavoring to locate these documents. Plaintiffs seek discovery from Lupin to prove a speculative and counterfactual theory, namely, that Lupin somehow could have launched generic Exforge and generic Exforge HCT earlier than it did. The evidence produced by Lupin demonstrates conclusively that Plaintiffs' theory is false. Thus, Lupin cannot provide an estimate of the time and effort it would expend to comply with requests to provide additional evidence that contradict the documents it has already produced.

III. PLAINTIFFS SHOULD REIMBURSE LUPIN FOR THE COSTS IT HAS INCURRED TO DATE AND ANY ADDITIONAL COSTS ASSOCIATED WITH THE MOTION TO COMPEL.

Lupin respectfully requests that the Court deny Plaintiffs' Motion in its entirety. However, if the Court requires Lupin to conduct additional searches in addition to the substantial production it (and Novel) has already made, Lupin respectfully requests that the Court order Plaintiffs to bear Lupin's reasonable costs of compliance. *Namenda*, 2017 WL 3822883 at *10 (ordering Plaintiffs to pay Lupin's costs of complying with the document subpoena.) Because

Rule 45 requires courts to minimize burdens on non-parties, cost shifting is “particularly appropriate in the context of subpoenas.” *US Bank N.A. v. PHL Variable Ins. Co.*, No. 12 Civ. 6811(CM)(JCF), 2012 WL 5395249, at *4 (S.D.N.Y. Nov. 5, 2012). To determine whether cost shifting is appropriate, courts look to “(1) whether the nonparty has an interest in the outcome of the case; (2) whether the nonparty can more readily bear the costs; and (3) whether the litigation is of public importance.” *Id.* Thus, courts in this District have held that where “the value of the discovery requested and the burden of production” are in dispute, “the prudent course is to allocate the costs of discovery in a manner that places the incentive on the parties to focus the production and minimize costs.” *Id.* Because Plaintiffs have refused to accept Lupin’s continuing good faith offers of compromise, Plaintiffs should bear the cost of any production this Court may order, as well as Lupin’s costs incurred to date to comply with the Subpoena.

CONCLUSION

For the foregoing reasons, Lupin respectfully submits that the Court deny Plaintiffs' Motion and award Lupin its fees and costs incurred in opposing the Motion and complying with the Subpoena.

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CERTIFICATE OF SERVICE

I, Zarema A. Jaramillo, hereby certify that on June 12, 2020, I caused a true and correct copy of **Memorandum of Law in Support of Third Parties Lupin Ltd. and Lupin Pharmaceuticals, Inc.’s Opposition to Plaintiffs’ Motion to Compel** to be served by ECF upon counsel of record.

By: /s/ Zarema A. Jaramillo